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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re application of:

Ferguson *et al.*

Appl. No. 09/817,229

Filed: March 27, 2001

For: **Method for Effecting
Neuroprotection**

Confirmation No. 8063

Art Unit: 1646

Examiner: Chernyshev, O.

Atty. Docket: 1669.0040001/SRL/BLS

Reply To Restriction RequirementCommissioner for Patents
Washington, D.C. 20231

Sir:

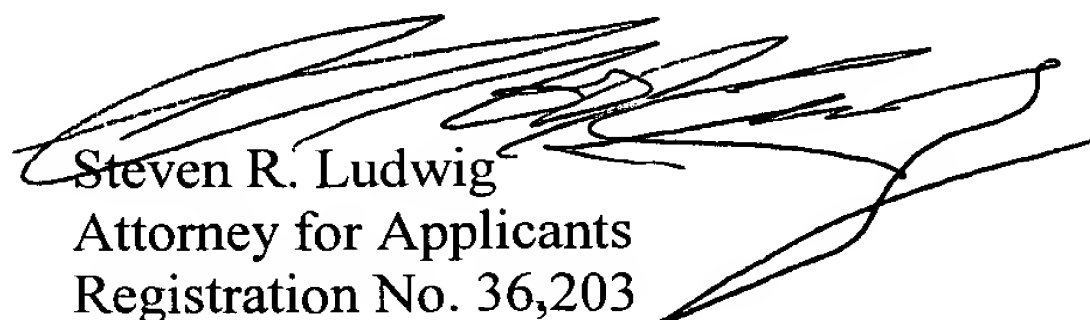
In reply to the Office Action dated January 8, 2002, requesting an election of one invention to prosecute in the above-referenced patent application, Applicants hereby provisionally elect to prosecute the invention of Group I, represented by claims 1-20. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

This election is made without traverse.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.


Steven R. Ludwig
Attorney for Applicants
Registration No. 36,203

Date: February 8, 2002

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Office Action Summary

Application No.

09/817,229

Applicant(s)

FERGUSON ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☒ Claim(s) 4 and 15-17 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in Paper No. 7 is acknowledged.

Claims 21 and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 7.

Claims 1-20 are under examination in the instant office action.

Claim Objections

2. Claims 15-17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.
3. Claim 4 is objected to because of the following informalities: the claim does not end with a period. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-20 are directed to a method of preventing damage to the excitable cells of a patient by means of administration of a compound, which increases potassium current in the excitable cells of a patient. On page 4 [0008] of the instant specification it is specifically expressed that "The present invention is based [...] on the discovery that the magnocellular neurons in the hypertensive subjects with increased central angiotensin-II lose their resistance to glutamate excitotoxicity as a consequence of endogenous angiotensin-II inhibiting IA." Thus, the scope of discovery is summarized above. It would require undue experimentation for a one skilled in the art to practice the Applicant's invention, as currently claimed, for the reasons that follow.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. In re Wands, 8 USPQ2d, 1400 (CAFC 1988).

First, according to definitions of the instant specification "excitable cells" include "neurons, such as interneurons, sensory neurons, and motor neurons, and cardiac myocytes" (page 8, [0036]). Thus, the claimed method encompasses prevention damage not only to the neurons of the central nervous system but also to the neurons of the peripheral nervous system (sympathetic and parasympathetic). The instant specification fails to provide any guidance for

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practicing the claimed method in reference to autonomic neurons, as well as cardiac myocytes. Information presented in the specification only relates to brain neurons and only to magnocellular neurons of the paraventricular nucleus (PVN) of the hypothalamus. The prior art does not offer any additional scientific support to indicate that practicing the claimed method would prevent damage to other "excitable cells". Second, the term "patient" is extremely broad and intends to refer, according to the instant specification, to a mammal. There is not enough guidance provided in the instant specification that would lead to conclusion that information presented in the specification regarding human subjects and working examples regarding rats as experimental model would be predictive to all other mammals.

Next, the amount of compounds, both discovered and not yet discovered, that increase potassium current in neurons is vast. There is no evidence of record, in the instant specification or prior art, that would suggest that any given compound that increases neuronal potassium current would be effective in preventing damage to the cells affected by an ischemic event.

The working examples of the instant specification are limited to histological analysis and electrophysiological recording of brain slices of hypothalamic area after intracranial injection of different factors, including saralasin. The experiments were done on normal rats, according to the examples and figures description. According to the detailed description of the invention, the experiments were carried out on spontaneously hypertensive rats (page 24 [0075]). One skilled in the art would not conclude that results of the study performed on brain slices of rats using saralasin as a compound that increases potassium current would be directly extrapolated to practice a method to prevent damage to the excitable cells of a patient during an ischemic event using any compound that increases potassium current.

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Finally, to practice such a method would require a knowledge of the route, duration and quantity of administration of a compound which increases potassium current to a subject and this information is not provided by the instant specification. The text on pages 8-32 of the instant specification clearly fails to supply the guidance that would be needed by a routine practitioner. The instant specification has also failed to disclose how these parameters are to be determined, how a similar method was practiced in the art with a different agent. In the absence of this guidance a practitioner would have to resort to a substantial amount of undue experimentation involving the variation in the amount and duration of administration of compound which increases potassium current of the instant invention and in determining a suitable route of administration. The instant situation is directly analogous to that which was addressed in *In re Colianni*, 195 U.S.P.Q. 150,(CCPA 1977), which held that a "[d]isclosure that calls for application of "sufficient" ultrasonic energy to practice claimed method of fusing bones but does not disclose what "sufficient" dosage of ultrasonic energy might be or how those skilled in the art might select appropriate intensity, frequency, and duration, and contains no specific examples or embodiment by way of illustration of how claimed method is to be practiced does not meet requirements of 35 U.S.C. 112 first paragraph".

In view of the lack of teachings and unpredictability of the art set forth earlier, the instant specification is not found to be enabling for a method of preventing damage to the excitable cells of a patient by means of administration of a compound, which increases potassium current in the excitable cells of a patient. It would require undue experimentation and making a substantial inventive contribution for the skilled artisan to discover how to use Applicants' invention as currently claimed.

Conclusion

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.
March 8, 2002

OC

[Handwritten signature]
**JOHN ULM
PRIMARY EXAMINER
GROUP 10**